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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------------------------|----------------------|---------------------|------------------|
| 10/531,462 | 04/15/2005 | Mauro Napoletano | 270280US0PCT | 1366 |
| | 7590 04/17/200 AK, MCCLELLAND, | EXAMINER | | |
| 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | PESELEV, ELLI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |
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| SHORTENED STATUTORY | Y PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE | |
| 3 MO | NTHS . | 04/17/2007 | ELECTRONIC | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/17/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com oblonpat@oblon.com jgardner@oblon.com

| Office Action Summary | | Application No. | Applicant(s) | | | | |
|--|---|---|--|--|--|--|--|
| | | 10/531,462 | NAPOLETANO ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| • | | Elli Peselev | 1623 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| WHIC - Exter after - If NO - Failu Any r | ORTENED STATUTORY PERIOD FOR RECHEVER IS LONGER, FROM THE MAILING asions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory per to reply within the set or extended period for reply will, by state to reply with the set or extended period for reply will, by state ply received by the Office later than three months after the material part of the provided patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICATION 1.1.136(a). In no event, however, may a reply be tir- iod will apply and will expire SIX (6) MONTHS from ature, cause the application to become ABANDONE | N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133). | | | | |
| Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 14 | 4 February 2007 | | | | | |
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| <i>,</i> — | | | | | | | |
| , | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Dispositi | on of Claims | | | | | | |
| 4) Claim(s) 1-15 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. | | | | | | | |
| 6)⊠ | 6)⊠ Claim(s) <u>1-15</u> is/are rejected. | | | | | | |
| 7) | Claim(s) is/are objected to. | | • | | | | |
| 8) | Claim(s) are subject to restriction and | d/or election requirement. | • | | | | |
| Applicati | on Papers | | • | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| | 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| | application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | | | | | | | |
| Attachment | (s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date | | | | | | | |
| | nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date | 6) Other: | 5) Notice of Informal Patent Application6) Other: | | | | |

Application/Control Number: 10/531,462

Art Unit: 1623

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al (U.S. Patent No. 6,262,030) in view of Djokic et al (U.S. Patent No. 4,886,792).

Wu et al disclose closely analogous azithromycin antibiotics (see, for example, column 8). The only difference between the azithromycins disclosed by Wu et al and the claimed azithromycins is at the 3-position i.e. the reference's compounds contain a keto group at the 3-position, while the claimed compounds contain a hydroxy group at the 3-position. However, since Djokic et al disclose closely analogous antibiotics having hydroxy group at the 3-position and a process for preparing said compounds by removing a cladinose moiety (column 2), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to modify the

compounds disclosed by Wu et al at the 3-position in accordance with the teaching by Djokic et al because such a person would have expected the resulting compounds to have similar activity.

Applicant's arguments filed February 14, 2007 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Elli Peselev